2005 Recommendations of the International
Commission on Radiological Protection

The U.S. Nuclear Regulatory Commission (NRC) would like to thank the International Commission on Radiological Protection (ICRP) for the opportunity to provide comments on the draft 2005 Recommendations of the ICRP. The opportunity to submit and review other stakeholder comments on Commission documents is greatly appreciated. The NRC's was established to regulate the civilian commercial, industrial, academic, and medical uses of nuclear materials to enable our nation to use radioactive materials for beneficial civilian purposes while ensuring that public health and safety, common defense and security, and the environment are protected. We believe this mission is consistent with the aim and goals of the ICRP. With this in mind, the NRC has reviewed the draft 2005 ICRP Recommendations and is providing the following general and specific comments for consideration by the Main Commission.

It is the NRC's understanding that the "foundation" documents have been delayed and may not be available until Spring 2005, the ICRP plans to delay issuance of the draft 2005 Recommendations until 2006 or later, and the ICRP intends to solicit another round of stakeholder comments after the draft 2005 Recommendations are revised. The NRC fully endorses this plan of action. The intent of the general and specific comments provided is to support this decision and assist the ICRP Secretariat and Main Commission refine and simplify the current system of radiological protection while maintaining stability in national and international regulations where practicable. We look forward to future opportunities to provide comment and interact with the ICRP as the pending foundation documents are made available for public comment and these draft recommendations are further considered.

General Comments

1. There are a number of instances where the draft 2005 Recommendations appear to be a "work-in-progress". There are at least four major "foundation" documents that should provide the technical basis for the draft 2005 Recommendations, but these documents are not available for stakeholder review, and will not be available for review until after the next Main Commission meeting in March 2005. Consequently, a thorough review of the draft 2005 Recommendations cannot be completed until the information contained in these documents is publically available. The NRC believes that the ICRP should delay finalizing the draft 2005 Recommendations until the "foundation" documents have been completed, posted on the ICRP's Web site, and reviewed by the international community. A 2-year delay also would afford the ICRP the opportunity to review the U.S. National Academies' Biological Effects of Ionizing Radiation report (BEIR VII) to ensure consistency between that report and the ICRP's consolidated recommendations. Similarly, the next United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) report is expected to provide a comprehensive review of new scientific data on the biological effects of ionizing radiation and should be considered by the ICRP before it finalizes its' recommendations.

2. The draft 2005 Recommendations, when finalized, will document an improved understanding of the health effects of ionizing radiation exposure which should improve realism in conducting risk informed regulation. However, the draft 2005 Recommendations will not substantially improve public health and safety for NRC-licensees. The majority of occupational

exposures, as reported in NUREG-0713, are below the suggested constraints and dose limits. Adopting and implementing the draft 2005 Recommendations may necessitate time-consuming, contentious, and possibly expensive changes to documents prepared by national regulatory authorities and radioactive material licensees with little or no improvement in public health and safety. The ICRP should reconsider the need for many of the changes that will necessitate modification of existing regulatory programs that already achieve the protection objectives of the ICRP.

3. ICRP appears to be moving away from risk-based considerations for setting the values of constraints. One of the strengths of the 1990 Recommendations was its risk-based foundation. The logic of separating practices and interventions was clear, and the basis of the 1990 dose limits in acceptability of risk was defensible, even if there were different views about what is acceptable. The NRC is uncertain whether the same can be said of the proposed maximum dose constraints. The draft 2005 Recommendations use background radiation exposure as a benchmark for determining whether regulatory action is needed. A discussion regarding the acceptability of risk should be included as part of these recommendations. One consequence of moving away from risk as a basis for setting constraints is that it becomes unlikely that a unified (i.e., harmonized) system for controlling chemical and radioactive pollutants can be developed.

4. The technical basis to support a recommendation to modify the tissue weighting factors and nominal risk coefficients is not adequately presented. Furthermore, it is unclear how the nominal risk coefficients proposed can be applied to the global community if they are based in part on early cancer diagnosis and treatment success. The ICRP is encouraged to clearly elaborate the underlying basis for selection of the tissue weighting factors, and explain how these factors can be applied to any global population.

5. ICRP proposes adopting a system of protection that appears to consist of multiple tiers of constraints and limits. The relationship between limits and the various meanings of constraints is not adequately described, and in some cases the terms are used inconsistently. For example, restrictions on individual dose from specified sources (e.g., source-constraints) "provide a level of protection for individuals that should be considered as obligatory and not maintaining these levels of protection should be considered as a failure." It is unclear how this differs from the legal usage of the term "limit" by regulatory agencies. Furthermore, adopting the proposed tiered system of maximum constraints may not promote international consistency (i.e., harmonization) in the establishment of source constraints because the draft 2005 Recommendations encourage national authorities to establish country-specific constraints with values less than the ICRP recommended maximum constraint. This strategy will not simplify or promote coherence within the general system of radiological protection. ICRP is strongly encouraged to clarify these terms and their intra-relationship with each other.

6. Although the role of collective dose in a system of radiological protection has been substantially revised, the ICRP should provide additional guidance on how collective dose should be applied and under what circumstances it should not be used. Collective dose, when properly constrained to specific time periods, populations, and locations, is a useful regulatory analysis tool. Conversely, collective dose can be misused in certain circumstances and such misapplications should be avoided. The draft 2005 Recommendations suggest the use of a dose matrix for decision making, but no details are provided on the quantitative or qualitative uses of such a matrix. It is not obvious whether the dose matrix replaces the use of collective

dose, or provides a framework for the appropriate application of the concept. The ICRP is encouraged to clarify the conceptual considerations as well as in practical implementation of collective dose and the dose matrix.

7. The ICRP has provided significant new recommendations in the area of exemption and exclusion. However, the draft 2005 Recommendations do not present a clear and consistent approach to managing low doses and controlling small quantities of radioactive material. For example, the ICRP system of radiological protection generally applies to any actual or potential exposure, whatever its magnitude. In the case of very low levels of exposure (e.g., <10 μSv per yr) from radioactive materials, application of the optimization principle would indicate that no additional protective action needs to be undertaken. Yet, some items will be excluded from regulatory control without regard to the question of whether anything within reason can be done to control them. Finally, the draft 2005 Recommendations suggest that materials with activity concentrations less than or equal to <10 μSv per yr may be considered to be nonradioactive and thus excluded from radiological control. The ICRP is encouraged to reexamine the conflicts within the numeric and conceptual recommendations throughout the document and present a clear and coherent approach.

8. NRC is unaware of evidence that suggests the existing regulatory framework to protect the public is inadequately protective of other species. In the absence of such evidence, the effort to develop a separate framework for the protection of other species will result in a significant expenditure of resources and is likely to detract from on-going efforts to improve, integrate, and harmonize the existing framework of protection of the public health and safety and the environment. The development of specific recommendations/standards for the protection of non-human species should be left to individual governments, so that flexibility in implementation is maintained at the national level. Therefore, the NRC strongly recommends that Section 11 and Appendix B should be removed from the document. If the Section must be retained, it is suggested that a caveat be inserted to indicate that this is a work-in-progress, and the Section is intended mainly to indicate a future direction of ICRP.

Specific Comments:

1. Page 12, Paragraph 13:

   It is recommended that the term “lifestyles” be removed from this paragraph. This may be interpreted as encouraging the frivolous use of radiation for purposes for which such use is not necessary. The “and lifestyles” could be deleted without detriment to the rest of the sentence.

2. Page 12, Paragraph 14:

   The first sentence should be modified. Scientific data cannot be used to develop ICRP’s primary aim, since such data is value-neutral. Therefore, the statement that “This aim cannot be achieved solely on the basis of scientific data” is incorrect. The sentence should indicate that the draft 2005 Recommendations represent value judgements based on scientific data.

3. Page 12, Paragraph 17:

   It would help if some words are added to indicate what types of sources would fall outside the classification of “practice.” In other words, “controllable sources” appear to include practices as well as non-practices, and the draft 2005 Recommendations should say something about this area of “non-practices” that is still apparently included within the scope of the recommendations.

4. Page 13, Paragraph 22:

   The paragraph should be simplified. The major points of the paragraph are: existing sources (give a couple of examples) are covered by the draft 2005 Recommendations, actions are usually only possible on the pathways of exposure, and some existing situations may be excluded from the scope of the draft 2005 Recommendations. Distinction between natural and artificial sources is not necessary.

5. Page 13, Section 2.3:

   The discussion in this section mixes the concept of exemption and exclusion which may be misunderstood. Rather, it might be better to move this discussion to Section 8 or initiate a more general description of authorization in the context of controllable sources and then describe exemption as one type of authorization decision.

6. Page 13, Paragraph 24:

   This paragraph states that “In principle, it [exclusion] can be applied to both natural and artificial sources of radiation although in practice it will largely be of use in the control of natural sources.” It is likely that this statement will cause difficulties when implementing the draft 2005 Recommendations to artificial sources. It also violates the stated aim of the draft 2005 Recommendations, namely to apply uniform criteria to all sources of exposure. It is suggested that this sentence be removed or the idea behind it should be elaborated to avoid misunderstanding.

7. Page 13, Paragraph 25:

   This paragraph states that “Sources and exposures that are not excluded are within the scope of the system of protection. These sources and exposures should be subject to appropriate authorization by the relevant regulatory authority.” Since natural radioactivity may fall in this category, it is suggested that the term “should” in the above sentence be replaced with “may” to avoid future difficulties in which the regulatory agency does not explicitly exclude or exempt such sources but nevertheless maintains the option to eventually impose regulatory requirements if it appears warranted.

8. Page 14, Paragraph 31:

   The ICRP draft 2005 Recommendations should identify the features that are influencing the format of the proposed recommendations and how the format has been influenced, as it is not obvious to the readers. The ICRP has not provided evidence that even suggests that there are health effects that can be directly attributed to the 1 or 2 mSv

received each year from natural background radiation nor any additional, incremental exposure received from sources that are influenced by the Commission's recommendations. This paragraph currently describes the simple fact that no exposure is received in isolation and the incremental dose is an important consideration (assuming a linear, no threshold dose response model). The NRC recommends that the evidence for health effects from environmental exposures be presented.

9. Page 16, Paragraph 40:

   It would be helpful at this point to give a name to the absorbed dose, weighted by the RBE for the deterministic effect in question. Various names have been in the literature, such as Gy-equivalent, and it would helpful to have a uniform name for this quantity. The name given in ICRP-92 could be noted here and would be helpful.

10. Page 18, Paragraph 51:

    It is acknowledged that Sievert is used for two different quantities. However, introduction of a new unit for radiation weighted dose may have a considerable impact on current regulations, guidance, and reporting requirements. The NRC recommends that the unit Sievert be retained for both quantities.

11. Page 27, Paragraph 93:

    Delete entire paragraph. In this paragraph and several paragraphs to follow, the Commission discusses what it plans to undertake, what it plans to publish, and/or what it plans to discuss in future documents. This information is more appropriate for the ICRP annual report, not a final publication.

12. Page 28, Paragraphs 96-98:

    It may be helpful to provide an explanation of why the Commission decided to abandon the terms stochastic and deterministic in favor of cancer development and tissue reactions. The NRC recommends retaining the terms stochastic and deterministic to avoid additional confusion.

13. Page 28, Paragraph 96:

    Information to be published by ICRP Committee 1 in 2005 should be included in this document and not in some future document. As is discussed in later comments, the scientific basis for the new nominal risk and detriment coefficients is unclear. Materials contained in the "to be published" document is needed in this Publication.

14. Page 30, Paragraph 101:

    The ICRP appears to be more emphatic that the linear, no-threshold dose response model is the most correct basis for the system of radiological protection claiming that the "weight of evidence" implies that a linear, no-threshold dose response is the correct model. Strict adherence to the linear, no-threshold model will impact stakeholder acceptability of authorization decisions like exemption or exclusion. The NRC

recommends that the ICRP clearly describe the scientific basis for its decision to more emphatically endorse the linear, no-threshold dose response model.

15. Page 32, Paragraph 112:

    The nominal probability coefficient for fatal cancer among working persons is not cited in the entire publication. The text suggests that the mortality coefficients are lower in this document compared to those cited in Publication 60 -- presumably due to earlier cancer diagnosis and more effective treatment. However, it is unclear if this trend is observed globally or just among the Asian/European-American subgroup used by ICRP. It is recommended that the ICRP clarify to whom the risk coefficients apply and how the risk coefficients are adjusted for dose and dose rate reduction factors.

16. Page 35, Paragraph 126:

    The environmental pathway generally links source and exposure (not exposure and dose). Reword the second to last sentence to say, "For convenience, the environmental pathway is taken to include the whole network of events, from source to exposure and include the link between the exposure and dose."

17. Page 35, Paragraph 132:

    "They (restrictions on individual dose from specified sources) provide a level of protection for individuals that should be considered as obligatory and not maintaining these levels of protection should be regarded as a failure." The NRC interprets this to be a dose limit, not a dose constraint. Legal usage of the term "limit" should be discussed in greater detail. In addition, the ICRP should clarify (1) the relationship between the "legal limit = maximum constraint", (2) the constraint established by a licensee for their particular practice (which should be less than the maximum both to take account of other sources and to avoid breaking the legal boundary), and (3) the implication(s) maximum constraints will have on interventions and emergency response.

18. Page 36, Paragraph 133:

    It may help to clarify the statement "The Commission recommends the use of quantitative dose constraints to protect the most exposed individuals from all identified controllable sources." From the definition of a constraint as being applicable to a single source, one could infer that the recommendation would be applied to each source independently, and that the most exposed individual is likely to be different for each source. If this is the intended meaning, it would be beneficial to state it explicitly. If not, then the intended meaning should be more clearly stated.

19. Page 36, Paragraph 136:

    A discussion of the hierarchy of constraints would be appropriate in this paragraph. The Commission is recommending maximum constraints and source constraints. National authorities would be expected to enact constraint (e.g., limits) that are generally below the maximum recommended values. Finally, licensees will need to establish administrative constraints to ensure they do not exceed the constraints established by

the national authority. These relationships are not articulated, nor is it apparent how a consistent and coherent framework of radiological protection is being fostered.

20. Page 36, Paragraph 137:

The second sentence indicates that "the constraint represents the level of dose or risk where action to reduce that dose or risk is virtually certain to be warranted." This appears to be inconsistent with the earlier statement that the restriction is mandatory. It also is not clear how exceeding the source constraint in an existing exposure situation could be a statutory offence. There could be emergency situations where it might be necessary to exceed the maximum constraint if failure to take the action resulted in a greater detriment.

21. Page 37, Figure (2):

The upper panel of the figure is inconsistent with the separation of occupational, public, and medical exposures. The notation for "Radiology" should be removed from the public's exposure to multiple regulated sources. Although the public is protected from exposures to medical sources, the distinction with prescribed medical exposure is not evident. In the lower panel, the reactor plant should be removed and another piece of clip art (e.g., waste) inserted. The reactor plant is a single entity that contains multiple sources of exposure. As depicted, it is unclear whether the worker is exposed to a single source, for which a constraint applies for the site, or to different sources (e.g. radioactive waste, maintenance, and calibration) each of which is subject to a different constraint. The same issue applies to the nurse. The notation of transporting a patient should be added to the second panel.

Conversely, the entire figure could be removed and the concept of exposure to multiple sources described only with text to avoid misinterpretation.

22. Page 38, Paragraph 145:

This section recommends estimating exposure to "the most exposed individual or to the most highly exposed group of individuals (the critical group)." The first comment is that in some cases, it makes a significant difference whether the most exposed individual or the critical group are considered. If the critical group is considered, it is not stated whether the dose is to the average member of the critical group or to the most exposed member of that group. Finally, the critical group is not necessarily the "most highly exposed group" since age-dependent risk may make the critical group one that is not the most highly exposed. The ICRP should clarify whether these decisions and definitions are to be made by the national regulatory authority, and if so, what guidance the ICRP will provide to ensure uniformity (harmony) between different national authorities.

23. Page 41, Paragraphs 158 - 161:

The concept of "need for action" should be clarified. As presented, it could be interpreted as a need for intervention, but this is apparently not the intent. The ICRP

appears to be advocating a graded approach to regulation, which is fine in principle, but this idea needs to be elaborated at this point in the guidance.

24. Page 42, Paragraph 160:

    Clarify "within the natural background range" in the last sentence. The NRC recommends that the value for background cited by UNSCEAR be used (0.8 to 2.4 mSv/yr).

25. Page 42, Paragraph 164:

    The use of the term constraint is defined by the Main Commission as source-related. When applied to occupational exposures, the recommended constraint is 20 mSv/yr. Many workers work at several locations during a year. The ICRP should clarify whether or not workers are subject to separate 20 mSv/yr constraints for each site at which they work during a year or if a single maximum constraint applies.

26. Page 43, Table 7:

    An effective dose of 0.01 mSv in a year is not a maximum constraint and should be deleted from Table 7 to avoid confusion. The final bullet in paragraph 164 describing the rationale for a minimum constraint should be a separate paragraph to minimize confusion.

27. Page 44, Paragraph 172:

    The concept of critical group should only be applied to situations where the exposure of individuals (members of the public) is a large fraction of the 1 mSv constraint. The process to define a critical group on a site-specific basis typically requires considerable research and data gathering and analysis, as well as on-going maintenance of the data. The cost of conducting and updating such analyses may be better justified at higher exposure levels. The use of a hypothetical maximally exposed individual should suffice as a surrogate for the more rigorous critical group when the exposures are a small fraction of the constraint (or limit). This paragraph should be revised to allow a graded approach with this alternative.

28. Page 45, Paragraph 175:

    The dose limits contained in Publication 60 have been retained. The supplementary equivalent-dose limit to the surface of the woman's abdomen is 2 mSv for the remainder of the pregnancy (Publication 60, Paragraph 178). Therefore, the last sentence should be revised to indicate the Commission is recommending a new "administrative constraint" equal to 1 mSv during the remainder of the pregnancy to protect the fetus.

29. Page 45, Paragraph 176:

    Delete last sentence referring to guidance under development unless it will be included in the final version of this publication.

30. Page 45, Paragraph 177:

    Clarify whether the use of the term “limit” in the second sentence is intended to describe minimum constraint (0.01 mSv per year) or annual dose limit (1 mSv).

31. Page 45, Paragraph 178:

    In line 2, delete “(paragraph 146)” because this paragraph addresses medical exposure, not radon-222 exposures as controllable sources.

32. Page 46, Paragraph 180:

    The upper levels of radon cited in Table 8 do not appear to correlate with the effective dose of 10 mSv per year described in the preceding paragraph nor a maximum constraint of 20 mSv cited in Table 7. Rather, the two maximum constraints for radon more closely approximate an effective dose of 15 mSv (see UNSCEAR 2000, Annex B, paragraph 153). Describe or cite the methodology used to generate these values.

    Clarify the use of the phrase “levels” in sentences 5 and 6. Some readers may confuse levels with the term “maximum constraint” which is not being discussed in these two sentences.

33. Page 47, Paragraph 185:

    In the fourth sentence from the bottom of the paragraph, the citation is inaccurate. Revise the sentence to read “...the limit for public exposure should be expressed...”

34. Page 47, Paragraph 186:

    The conclusion can be drawn from the discussions in Sections 3.3.2, “Radiological protection quantities: Averaging of dose”; 3.5.2,” Control of tissue reactions”; and 6.5.2, “Limits for individual organs and tissues”, that (with the exception of the skin, hands and feet, and lense of the eye) doses in excess of the non-stochastic thresholds for damage to the various tissues and organs, are permissible over some small fraction of those tissues or organs. It is not clear if this is was intended by the Commission. The advisability of using the dose, averaged over the entire tissue or organ, when assessing the effective dose resulting from partial body, or other non-uniform exposure situations (i.e., when wearing a shielded apron, where only the head and arms receive significant exposure), should be addressed directly in this document.

35. Page 48, Table 9:

    Footnote 2 to the table indicates that dose to the skin is to be averaged over 1 cm^2 as opposed to averaging over the entire organ when determining effective dose. However, recent work by the NCRP (Report no. 130, “Biological Effects and Exposure Limits for Hot Particles”) indicates that a 500 mSv limit averaged over 10 cm^2 is sufficient to prevent significant tissue reactions in the skin, even for the worse case non-uniform (hot particle) exposure. The Draft 2005 Recommendations should be revised with averaging over 10 cm^2 as the basis for the skin dose limit.

Delete the separate limit of 500 mSv given for the hands and feet in Table 9. The only tissue of concern in this situation is the skin, which already is covered by the 500 mSv skin dose limit listed in the table.

36. Page 48, Paragraph 187:

Reword first sentence to “The Commission’s dose or risk constraints are a necessary but incomplete condition to ensure...” Although a minor change, the sentence could be misinterpreted to mean that a risk or dose constraint is not adequately protective. Rather, the constraint is only one element in a system of radiation protection.

37. Page 49, Paragraph 190:

In the first sentence, change to “aimed at reducing or preventing exposures...” Not only is optimization aimed at preventing exposures when they can be prevented, but also at reducing exposures that cannot be avoided.

38. Page 49, Paragraph 191:

Optimization does not cause exposures. Reword to read: “The exposures from a source that has been continuously optimized reflect levels which, at some point in time...”

39. Page 50, Paragraph 194:

Delete the last two sentences. The introduction of the “best available technology not entailing excessive costs” as the equivalent to optimization introduces some confusion on principles and process. In normal usage, best available technology is a very different conceptual framework, starting from a technology base, and then determining if can be introduced on a wide scale. Success is generally not judged on the basis of a minimization of dose or released quantity of material, but rather on whether the technology is the best available, irrespective of how well current or previous technologies may be working to reduce exposures. It is not at all obvious how this is consistent with the maximum constraint and optimization framework.

40. Page 50, Paragraph 195:

In the discussion of optimization, ICRP states that the basic role of optimization is to foster a safety culture. Rather than implying that a safety culture is an outcome of optimization, it might be better to describe those characteristics and attitudes that constitute a safety culture, and the role played by optimization in achieving those objectives.

41. Page 50, Paragraph 196:

It is unclear how the ICRP envisions that stakeholder involvement be incorporated into the optimization of radiation exposures for a given practice. Once an activity or practice is justified and authorized by a national authority, the controls and decisions, employed to ensure dose is optimized, are carried out at an operational level. It would be impractical to attempt to accommodate input from all stakeholders into each of these

operational decisions during the conduct of the particular practice. There should be a distinction drawn between an overall (or high level) optimization/ALARA scheme, specific for each practice, and the day to day implementation of that scheme.

42. Page 51, Paragraph 200:

The statement that "...a large dose to a small number of people is not equivalent to a small dose to many people.." needs to be qualified. The two conditions are equal if one accepts the linear no-threshold dose-response model, and they are equal from a net detriment point of view. A qualification should be added that, although the two situations are equal from an overall detriment consideration, they are not considered equal from an ethical perspective in a system in which protection of the individual, as opposed to collective detriment, is the major consideration.

It should also be recognized that most of the misuses of collective dose have occurred when dose to the public is being calculated. This paragraph should recognize that it is both useful and desirable to apply the concept of collective dose to occupational exposure. Experience has shown that collective dose is a very useful figure of merit when judging the efficacy of an occupational ALARA program.

43. Page 51, Paragraph 203:

If the information addressed by Committee 4 is relevant to these draft recommendations, then include the material. Otherwise, delete the citation.

44. Page 52, Paragraph 204:

In the last sentence, clarify what situation is being referred to. A clear, logical link between the recommendations for constraints and optimization, and the implementation of exclusion and exemption, is needed.

45. Page 52, Paragraph 205:

The Commission should clearly delineate the concepts of exemption and exclusion because they have vastly different regulatory impacts.

46. Page 52, Paragraph 206:

The values appear to provide a definition of what is to be considered radioactive. Yet, in some cases the values may be greater than the minimum value for a constraint. The ICRP should consider providing greater explanation to provide a linkage between the need for action, with dose or risk implications of such values, and also a delineation of the point at which no further optimization efforts are needed.

47. Page 53, Table 10:

Potassium-40 is an abundant natural radioisotope that should not be included in this exclusion table. If retained, the ICRP should clarify how consumer products like salt substitute (KCl, 15.4 Bq/g) and fertilizer containing potash (K_20) would be treated within

the scope of the draft 2005 Recommendations since they may exceed the exclusion activity concentration of 10 Bq/g.

48. Page 54, Paragraph 215:

    Delete last sentence. This is beyond the scope of the draft 2005 Recommendations.

49. Page 55, Paragraph 222:

    It may be helpful to clearly say that these diagnostic reference levels are not constraints, and are not intended by the Commission to be used in such a way.

50. Page 55, Paragraph 225:

    Provide a rationale for why exposures to helpers and care givers are treated differently than members of the public. Describe what, if any, restrictions on exposure to children or pregnant woman should be adopted in situations where exposures will occur from patients discharged from hospitals following diagnostic or therapeutic medical procedures. The issue of children and pregnant family members is not addressed and exposures of several mSv per episode may not be “reasonable” for these groups.

51. Page 56, Paragraph 226:

    Delete reference to insurance companies requiring individuals to receive medical exposure. This is beyond the scope of the draft 2005 Recommendations.

52. Page 56, Paragraph 227:

    The release of patients with permanent implants is not addressed. The ICRP should describe what restrictions, if any, are reasonable.

53. Page 57, Paragraph 230:

    A question of consistency may be raised by this paragraph, since the Commission recommendations have moved to incidence and other factors while this presentation remains focused on attributable death. Consider revision to address cancer incidence, not mortality.

54. Page 57, Paragraph 234:

    Recognizing that values for generic risk constraint already exist in the Commission’s publications, it is still difficult to understand why the risk constraint should be set on a completely different basis (i.e., on what has routinely been achieved in normal situations). This poses an inconsistency, and could conceivably lead to overemphasis for potential risks at the expense of normal exposures.

55. Page 58-59, Paragraphs 239 and 240:

It is not clear how applying the approach of potential exposure is at all satisfactory for hot particles. There are two distinct cases. First, for a hot particle on the skin, the NCRP has published material that led to NRC changing its definition of skin exposure so that it was not overly influenced by the localized acute damage that is easily repaired by the body (see comment 35). The second case might be how a survey would be conducted, and the criteria for any readings higher than normal. Again, the use of potential exposure is not straight forward or useful.

56. Section 11, The Protection of the Environment.

As discussed in the general comments, this section should be removed from the document. In addition, this chapter is completely different in character from the remainder of the document and does not provide recommendations or usable guidance that would be helpful to national organizations, nor does it further uniformity in protection of the environment. The chapter, and the corresponding Annex B, does not seem to fit in any logical way with the intent and presentation of recommendations that will foster consistency in protection by various national authorities and governments. It also seems inappropriate for "recommendations" to be a proposed course of work.

57. Page 60, Paragraph 242:

The Commission states there is a "need to harmonize approaches to industrial regulation". International harmonization is not identified as a specific aim of the draft 2005 Recommendations. The ICRP should clarify what it proposes to harmonize and whether or not it intends to modify the system of radiological protection to be risk-based. For example, US environmental regulation of industrial chemicals is goal oriented and risk-based, not dose-based. The maximum constraints described in the Draft for Consultation are dose-based.

58. Page 61, Paragraph 246:

Delete. The paragraph is not consistent with paragraph 242 or Annex B which suggests there are "demands upon regulators" that justify new efforts to protect the environment, not a conceptual gap.

59. Page 61, Paragraph 247:

A stated objective of environmental protection is "reducing the frequency of effects" likely to cause early mortality or reduce reproductive success. The way in which the objective is framed would seem to be in conflict with the other statements that there are not any particular concerns. The ICRP should articulate why this approach is needed if there is no particular environmental concern.

60. Page 66, Paragraph A11:

The composite population used in Annex A is different from population used in ICRP 60 as is the methodology to determine the nominal risk coefficient. Additional information is

needed to ascertain whether or not the tissue weighting factors and the nominal risk coefficients are applicable to the US population.

61. Page 70, Paragraph A31:

    The ICRP did not present a technical basis for setting q_{min} to 0.1. The Commission should provide sufficient technical basis so that its' recommended risk and detriment coefficients that are traceable, understandable, reproducible and have generic applicability.

62. Page 72, Tables A1 and A2:

    The presentation of nominal risk and detriment is neither transparent nor clear. By deviating from the methodology described in Publication 60, a more exhaustive explanation of where numbers were obtained and how values are computed is required. For example, it is not clear how the data for nominal risk coefficient (cases per 10,000 Person Years per Sv) were derived. The data for lethality coefficients (column 3) should be referenced. The ICRP should explain how the lethality coefficients cited in this table are appropriate for third world countries with less sophisticated cancer diagnostic and treatment capabilities. Since the cancer nominal risk and hereditary detriments have decreased relative to the Publication 60 values, a complete explanation of the methodology used to develop these numbers is needed for all Commission stakeholders to review and hopefully adopt. Otherwise, each national authority will consider adopting methodologies and values that are representative for their country.

63. Page 73, Paragraph A39:

    Delete bullet describing thyroid cancer. The tissue weighting factor for thyroid (0.05) is unchanged between ICRP Report 60 and these draft 2005 Recommendations. The thyroid weighting factor in Report 26 (0.03) was increased in Report 60 (0.05).